

109TH CONGRESS
2D SESSION

S. 2300

To amend the Federal Food, Drug, and Cosmetic Act with respect to market exclusivity for certain drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 16, 2006

Ms. STABENOW (for herself and Mr. LOTT) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to market exclusivity for certain drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Lower Prices Reduced
5 with Increased Competition and Efficient Development of
6 Drugs Act” or the “Lower PRICED Drugs Act”.

1 **SEC. 2. GENERIC DRUG USE CERTIFICATION.**

2 (a) IN GENERAL.—Section 505(j)(2)(A) of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 355(j)(2)(A)) is amended—

5 (1) in clause (vii), by striking “; and” and in-
6 serting a semicolon;

7 (2) in clause (viii), by striking the period and
8 inserting “; and”;

9 (3) by inserting after clause (viii) the following:

10 “(ix) if with respect to a listed drug product re-
11 ferred to in clause (i) that contains an antibiotic
12 drug and the antibiotic drug was the subject of any
13 application for marketing received by the Secretary
14 under section 507 (as in effect before the date of en-
15 actment of the Food and Drug Administration Mod-
16 ernization Act of 1997) before November 20, 1997,
17 the approved labeling includes a method of use
18 which, in the opinion of the applicant, is claimed by
19 any patent, a statement that—

20 “(I) identifies the relevant patent and the
21 approved use covered by the patent; and

22 “(II) the applicant is not seeking approval
23 of such use under this subsection.”; and

24 (4) in the last sentence, by striking “clauses (i)
25 through (viii)” and inserting “clauses (i) through
26 (ix)”.

1 (b) EFFECTIVE DATE.—The amendments made by
 2 this section shall apply to any abbreviated new drug appli-
 3 cation under section 505(j) of the Federal Food, Drug,
 4 and Cosmetic Act (21 U.S.C. 355(j)) that is submitted
 5 on, before, or after the date of enactment of this Act.

6 **SEC. 3. PREVENTING ABUSE OF THE THIRTY-MONTH STAY-**
 7 **OF-EFFECTIVENESS PERIOD.**

8 (a) IN GENERAL.—Section 505(j)(5)(B)(iii) of the
 9 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 10 355(j)(5)(B)(iii)) is amended—

11 (1) in the second sentence by striking “may
 12 order” and inserting “shall order”; and

13 (2) by adding at the end the following: “In de-
 14 termining whether to shorten the thirty-month pe-
 15 riod under this clause, the court shall consider the
 16 totality of the circumstances, including whether the
 17 plaintiff sought to extend the discovery schedule, de-
 18 layed producing discovery, or otherwise acted in a
 19 dilatory manner, and the public interest.”.

20 (b) EFFECTIVE DATE.—The amendments made by
 21 this section shall apply to any stay of effectiveness period
 22 under section 505(j)(5)(B)(iii) of the Federal Food, Drug,
 23 and Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iii)) pending
 24 or filed on or after the date of enactment of this Act.

1 **SEC. 4. ENSURING PROPER USE OF PEDIATRIC EXCLU-**
 2 **SIVITY.**

3 (a) DRUG PRODUCT.—Section 505A of the Federal
 4 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
 5 amended by striking “drug” each place it appears and in-
 6 serting “drug product”.

7 (b) MARKET EXCLUSIVITY FOR NEW DRUGS.—Sec-
 8 tion 505A(b) of the Federal Food, Drug, and Cosmetic
 9 Act (21 U.S.C. 355a(b)) is amended—

10 (1) in the matter preceding paragraph (1), by—

11 (A) striking “health” and inserting “thera-
 12apeutically meaningful”;

13 (B) striking “and” after “(which shall in-
 14clude a timeframe for completing such stud-
 15ies),”; and

16 (C) inserting “, and based on the results
 17of such studies the Secretary approves labeling
 18for the new drug product that provides specific,
 19therapeutically meaningful information about
 20the use of the drug product in pediatric pa-
 21tients” after “in accordance with subsection
 22(d)(3)”;

23 (2) in paragraph (1)(A)—

24 (A) in clause (i), by—

25 (i) striking “the period” and inserting
 26 “any period”; and

(ii) inserting “that is applicable to the drug product at the time of initial approval” after “in subsection (j)(5)(F)(ii) of such section”; and

(B) in clause (ii), by—

(i) striking “the period” and inserting “any period”; and

(ii) inserting “that is applicable to the drug product at the time of initial approval” after “of subsection (j)(5)(F) of such section”; and

(3) in paragraph (2)—

(A) in subparagraph (A)—

(i) in clause (i), by striking “a listed patent” and inserting “a patent that was either listed when the pediatric study was submitted to the Food and Drug Administration or listed as a result of the approval by the Food and Drug Administration of new pediatric labeling that is claimed by the patent, and”; and

(ii) in clause (ii) by striking “a listed patent” and inserting “a patent that was either listed when the pediatric study was submitted to the Food and Drug Adminis-

tration or listed as a result of the approval
by the Food and Drug Administration of
new pediatric labeling that is claimed by
the patent, and”; and

(B) in subparagraph (B), by striking “a
listed patent” and inserting “a patent that was
either listed when the pediatric study was sub-
mitted to the Food and Drug Administration or
listed as a result of the approval by the Food
and Drug Administration of new pediatric label-
ing that is claimed by the patent, and”.

(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED

DRUGS.—Section 505A(c) of the Federal Food, Drug, and
Cosmetic Act (21 U.S.C. 355a(c)) is amended—

(1) in the matter preceding paragraph (1), by—

(A) striking “health” and inserting “thera-
peutically meaningful”;

(B) striking “and” after “the studies are
completed within any such timeframe,”; and

(C) inserting “, and based on the results
of such studies the Secretary approves labeling
for the approved drug product that provides
specific, therapeutically meaningful information
about the use of the drug product in pediatric

1 patients” after “in accordance with subsection
2 (d)(3)”;

3 (2) in paragraph (1)(A)—

4 (A) in clause (i)—

5 (i) by striking “the period” and in-
6 serting “any period”; and

7 (ii) by inserting “that is applicable to
8 the drug product at the time of initial ap-
9 proval” after “in subsection (j)(5)(F)(ii) of
10 such section”; and

11 (B) in clause (ii)—

12 (i) by striking “the period” and in-
13 serting “any period”; and

14 (ii) by inserting “that is applicable to
15 the drug product at the time of initial ap-
16 proval” after “of subsection (j)(5)(F) of
17 such section”; and

18 (3) in paragraph (2)—

19 (A) in subparagraph (A)—

20 (i) in clause (i), by striking “a listed
21 patent” and inserting “a patent that was
22 either listed when the pediatric study was
23 submitted to the Food and Drug Adminis-
24 tration or listed as a result of the approval
25 by the Food and Drug Administration of

1 new pediatric labeling that is claimed by
 2 the patent, and”; and

3 (ii) in clause (ii), by striking “a listed
 4 patent” and inserting “a patent that was
 5 either listed when the pediatric study was
 6 submitted to the Food and Drug Adminis-
 7 tration or listed as a result of the approval
 8 by the Food and Drug Administration of
 9 new pediatric labeling that is claimed by
 10 the patent, and”; and

11 (B) in subparagraph (B), by striking “a
 12 listed patent” and by inserting “a patent that
 13 was either listed when the pediatric study was
 14 submitted to the Food and Drug Administra-
 15 tion or listed as a result of the approval by the
 16 Food and Drug Administration of new pediatric
 17 labeling that is claimed by the patent, and”.

18 (d) THREE-MONTH EXCLUSIVITY.—Section 505A of
 19 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 20 355a) is amended by—

21 (1) by striking “six months” each place it ap-
 22 pears and inserting “three months”;

23 (2) by striking “six-month” each place it ap-
 24 pears and inserting “three-month”;

1 (3) by striking “6-month” each place it appears
2 and inserting “three-month”;

3 (4) in subsection (b)(1)(A)(i), by striking “four
4 and one-half years, fifty-four months, and eight
5 years, respectively” and inserting “four years and
6 three months, fifty-one months, and seven years and
7 nine months, respectively”; and

8 (5) in subsection (c)(1)(A)(i), by striking “four
9 and one-half years, fifty-four months, and eight
10 years, respectively” and inserting “four years and
11 three months, fifty-one months, and seven years and
12 nine months, respectively”.

13 (e) DEFINITION.—Section 505A of the Federal Food,
14 Drug, and Cosmetic Act (21 U.S.C. 355a) is amended by
15 adding at the end the following:

16 “(o) DRUG PRODUCT.—

17 “(1) IN GENERAL.—For purposes of this sec-
18 tion, the term ‘drug product’ has the same meaning
19 given such term in section 314.3(b) of title 21, Code
20 of Federal Regulations (or any successor regulation).

21 “(2) SEPARATE DRUG PRODUCTS.—For pur-
22 poses of this section, each dosage form of a drug
23 product shall constitute a different drug product.”.

1 (f) TECHNICAL CORRECTIONS.—Section 505A of the
 2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)
 3 is amended—

4 (1) by striking “subsection (c)(3)(D)” each
 5 place it appears and inserting “subsection
 6 (c)(3)(E)”; and

7 (2) in subsection (n), by striking “under sub-
 8 section (a) or (c)” and inserting “under subsection
 9 (b) or (c)”.

10 (g) EFFECTIVE DATE.—The amendments made by
 11 this section shall apply to requests by the Secretary of
 12 Health and Human Services for pediatric studies under
 13 section 505A of the Federal Food, Drug, and Cosmetic
 14 Act (21 U.S.C. 355a) after the date of enactment of this
 15 Act.

16 **SEC. 5. CITIZEN PETITIONS AND PETITIONS FOR STAY OF**
 17 **AGENCY ACTION.**

18 Section 505 of the Federal Food, Drug, and Cosmetic
 19 Act (21 U.S.C. 355) is amended by adding at the end the
 20 following:

21 “(o) CITIZENS PETITIONS AND PETITIONS FOR STAY
 22 OF AGENCY ACTION.—With respect to any petition that
 23 seeks to have the Secretary take, or refrain from taking,
 24 any form of action relating to the approval of an applica-

1 tion submitted under subsection (b)(2) or (j), the following
2 shall apply:

3 “(1) NO DELAY OF APPROVAL.—The Secretary
4 shall not delay approval of an application submitted
5 under subsection (b)(2) or (j) while a petition is re-
6 viewed and considered. Consideration of a petition
7 shall be separate and apart from the review and ap-
8 proval of an application submitted under either such
9 subsection.

10 “(2) TIMING OF FINAL AGENCY ACTION.—The
11 Secretary shall take final agency action with respect
12 to a petition within six months of receipt of that pe-
13 tition. The Secretary shall not extend such six-
14 month review period, even with consent of the peti-
15 tioner, for any reason, including based upon the sub-
16 mission of comments relating to a petition or supple-
17 mental information supplied by the petitioner. If the
18 Secretary has not taken final agency action on a pe-
19 tition by the date that is six months after the date
20 of receipt of the petition, such petition shall be
21 deemed to have been denied on such date.

22 “(3) VERIFICATION.—The Secretary shall not
23 accept for review a petition unless it is signed and
24 contains the following verification: ‘I certify that, to
25 my best knowledge and belief: (a) this petition in-

1 includes all information and views upon which the pe-
2 tition relies; (b) this petition includes representative
3 data and/or information known to the petitioner
4 which are unfavorable to the petition; and (c) I have
5 taken reasonable steps to ensure that any represent-
6 ative data and/or information which are unfavorable
7 to the petition were disclosed to me. I further certify
8 that the information upon which I have based the
9 action requested herein first became known to the
10 party on whose behalf this petition is filed on or
11 about _____. I verify under pen-
12 alty of perjury that the foregoing is true and cor-
13 rect.’, with the date of the filing of such petition in-
14 serted in the blank space.

15 “(4) EXTENSION OF PERIOD.—The thirty-
16 month period referred to in subsection
17 (j)(5)(D)(i)(IV) shall automatically be extended by
18 the amount of time that lapses from the date that
19 the Secretary receives a petition and the date of
20 final agency action on that petition, without regard
21 to whether the Secretary grants, in whole or in part,
22 or denies, in whole or in part, that petition.”.

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